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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,202	09/14/2004	Sven Moesgaard	258563US0PCT	5104
22850	7590	10/11/2007	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			MCCORMICK, MELENIE LEE	
			ART UNIT	PAPER NUMBER
			1655	
			NOTIFICATION DATE	DELIVERY MODE
			10/11/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

Application No.

10/507,202

Applicant(s)

MOESGAARD ET AL.

Examiner

Melenie McCormick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' amendments with remarks filed 02 July 2007 have been received and considered.

New claims 12-20 have been added.

Claims 1-20 are presented for examination in the merits.

#### ***Claim Rejections - 35 USC § 112***

The previous rejection under 35 U.S.C 112 first paragraph has been withdrawn in view of Applicants' amendments.

The previous rejection under 35 U.S.C 112 second paragraph has been withdrawn in view of Applicants' amendments.

#### ***Claim Rejections - 35 USC § 102/103***

The previous rejection under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nogadawithana et al. has been withdrawn in view of Applicant's arguments.

#### ***Claim Rejections - 35 USC § 103***

The previous rejection under 35 U.S.C. 103(a) as being unpatentable over Nogadawithana et al. and Demicri et al. has been withdrawn in view of Applicant's arguments.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 6-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suhajda et al. (J. Trace Elements in Medicine and Biology) in view of Schrauzer (J. Nutrition) and Knowles et al. (J. Dairy Science).

Suhajda et al. teach a method of preparing a selenium-containing yeast product comprising cultivating *Saccharomyces cerevisiae* in a limited nutrient medium (i.e., minimal medium) containing glucose as the only carbon source (see e.g. page 44- Table 1). Suhajda et al. further teach that the method results in the accumulation of 1200-1400 µg/g of selenium in dried *Saccharomyces cerevisiae* (which is 1200-1400 ppm and within the range instantly claimed). Suhajda et al. further teach that the pH value used was about 4 and that increasing the pH leads to a lower selenium consumption and a simultaneously lower inorganic selenium content (see e.g. page 45 – Results). Suhajda et al. also teach that the yeast were separated from the medium by centrifugation and were then washed, filtered and dried (see e.g. page 44- Materials and Methods). Suhajda et al. also teach that the selenium yeast produced was scaled up for paramedical use (see e.g. page 46). Consequently, one of ordinary skill in the art

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would reasonably conclude that pharmaceutical grade starting materials should be used. Suhajda et al. do not explicitly teach that the concentration of ethanol produced is less than one percent, however, because the other conditions for producing the enriched yeast are the same or very similar to those instantly claimed, the amount of ethanol produced would necessarily also be the same or very similar to the amount instantly claimed. Suhajda et al. also do not explicitly teach that the content of L-selenomethionine constitutes at least 55% of the total organic selenium content and that the content of selenium in inorganic selenium compounds does not exceed 1% of the total selenium content, however, as evidenced by Schrauzer, *S. cerevisiae* accumulate 90% of the selenium in the form of L-selenomethionine and only trace amounts of organic selenium (see e.g. page 1653). Suhajda et al. do not explicitly teach that the method of producing selenium enriched yeast is performed using *Saccharomyces boulardii* or *Saccharomyces torula* or that the yeast are heat-treated or added to a food, drug, or dietary supplement.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a selenium yeast product following the method instantly claimed. One of ordinary skill in the art at the time the claimed invention was made would have had a reasonable expectation of success in doing so based upon the beneficial teaching of Suhajda et al. that a very similar method had been used. Although Suhajda et al. teach that the amount of inorganic selenium is around 5-6%, they also teach that increasing the pH leads to a lower inorganic selenium concentration.

Therefore, increasing the pH to a value higher than 4, particularly between 4 and 6, as

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claimed, would result in a lower amount of selenium in the form of inorganic selenium.

One of ordinary skill in the art would be motivated to use such a pH value based upon the guidance provided Schrauzer that selenium in the form of selenomethionine is a highly bioavailable form (see e.g. Schrauzer page 1654) and the well established knowledge that inorganic selenium (sodium selenite) is highly toxic (see e.g. Schrauzer page 1655). Therefore, a person of ordinary skill in the art would be motivated to produce a selenium yeast product with a high amount of bioavailable selenium and a low amount of toxic inorganic selenium in the form of sodium selenite. A person of ordinary skill in the art would also understand that the selenium enriched yeast product taught by Suhajda et al. is suitable for use as a supplement, food or drug, as Suhajda et al. teach that it is used for paramedical use. Furthermore, a person of ordinary skill in the art would understand that such a selenium enriched yeast product would be useful as a nutritional supplement as Schrauzer discloses the importance of selenium in animal nutrition and the use of selenium supplements (see e.g. page 1653- Abstract and page 1655). A person of ordinary skill in the art would also understand that a nutritional supplement containing the selenium enriched yeast should be heat treated in order to kill the yeast cells. This is particularly true in light of the disclosure of Knowles et al. that selenized yeast used in supplements are heat treated in order to kill the yeast (see e.g. page 430). The adjustment of particular conventional working conditions (e.g. adjusting the yeast cultivation so that a particular concentration of yeast is produced or adding particular nutrients to the medium according to their consumption rate during

cultivation of the yeast) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### **Conclusion**

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melenie McCormick  
Examiner  
Art Unit 1655



CHRISTOPHER R. TATE  
PRIMARY EXAMINER